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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/280,567	03/30/1999	THOMAS FRANK BUMOL	0409020136	5988

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/280,567

Applicant(s)
Bumol, TF et al

Examiner
Michael Brannock

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1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 7, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above, claim(s) 4, 5, and 7-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Nov 7, 2002 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Status of Application: Claims and Amendments:

Claims 1-35, and new claims 36-39 are pending.

Claims 4, 5 and 7-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, as set forth previously.

Applicant is notified that the amendments to the claims, but not to the specification, put forth in Paper 18 (12/19/00) and in Paper 20 (4/23/01) have been entered in full. Applicant is notified that the substitute specification submitted at Paper 27, 9/23/02 has not been entered. Additionally, Applicant was specifically advised in Paper 28, 10/8/02, that the substitute specification be submitted excluding the claims. However, the substitute specification submitted 11/7/02 (Paper 29) contained a copy of the original claims. Applicant is notified that the substitute specification submitted 11/7/02 has been entered, but the copy of the original claims, contained therein, has been marked-through by the examiner as being "duplicate". Thus, the amendments to the claims put forth in Paper 18 and 20 are valid and pending.

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Response to Amendment

Drawings

I. As per Applicant's request, Paper 29, 11/7/02, Figures 2 and 4 are now replaced with the new figures submitted 11/7/02. It is noted that Applicant asserts (11/07/02) that in the 9/20/02 amendment, replacement Figures 2 and 4 were inadvertently omitted from the submission. However, a replacement Figure 4 (received 9/23/02) is present in the file. This Figure, as well as the original Figure 4, has now been replaced the Figure 4 that was submitted 11/7/03.

Additionally, the pending drawings have been reviewed by the Draftsperson and are objected to as set forth in the attached PT0-948. Applicant is notified that as of May 3, 2001, examiners may not permit corrections to drawings to be held in abeyance. Appropriate correction is required in Response to this Office Action.

Claim Rejections - 35 USC § 112

I. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 6 and new claims 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 and 6 require an mFLINT protein. As there is no art recognized definition of an mFLINT protein, nor is such a definition provided in the specification,

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the metes and bounds of the claim Applicant is seeking protection for cannot be determined.

Applicant's arguments put forth in Paper 18, 12/29/00 are unpersuasive, as set forth previously, the specification defines the term "mFLINT" or "FLINT" by way of examples; these examples are insufficient to define the bounds of the claims. As acknowledged by Applicant, the term "FLINT" or "mFLINT" encompasses amino acid sequence variants of the disclosed sequences, yet the specification has not set forth the degree of variation that Applicant considers to define the boundary between what is and what is not a "FLINT" protein, and neither can such be reasonably inferred from the instant specification. It is suggested that the claims recite the actual SEQ ID NO:s of the proteins that Applicant considers to be "Flint" proteins.

It is noted that the additional bases for the rejection, set forth previously in item 4 of Paper 17, regarding the phrase "therapeutically effective amount", is withdrawn in view of Applicant's persuasive arguments and upon further consideration, MPEP 2173.05(c) III.

Claims 1-3 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treatment comprising the administration of a protein with the amino acid sequence depicted in Figure 4, does not reasonably provide enablement for methods of treatment comprising the administration of a protein termed "mFLINT" but which does not comprise the amino acid sequence depicted in Figure 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, as set forth previously.

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Applicant argues, essentially, that the claims are directed to a genus of proteins termed "FLINT" or "mFLINT", and that based on principles established in the art, substantial amino acid variation could be expected in this genus without disrupting the activity of the protein and its therapeutic value. This argument has been fully considered but not deemed persuasive. The state of the art as exemplified by Bowie et al., discussed previously, is that while a protein may be tolerant to amino acid changes, it is unpredictable as to which amino acids are tolerant to change based simply on sequence data. An independent assay of protein activity is required. Thus, the specification has merely presented to the skilled artisan an invitation to begin an extensive research plan of trial and error experimentation wherein amino acid positions in the protein of Figure 4 are randomly selected, then substituted, deleted or added, and then assayed for activity in the hope that amino acid sequence variants encompassed by the claims could be found that possess the activity required to function in the method as claimed. Such extensive random trial and error experimentation is unduly burdensome and would not be considered routine by one highly skilled in the art.

Applicant argues that while the number of FLINT variants is potentially enormous, the scope of the claims is limited to those variants that retain the biological and therapeutic utility of the parent molecule. This argument has been fully considered but not deemed persuasive. The skilled artisan appreciates that simply writing down or verbalizing that the variants must have a certain activity does not a substitute for providing guidance as how to make variants that have the activity.

Applicant argues that modern techniques for assaying mFLINT proteins exist in the art, and thus it would not require undue experimentation make and test variants. This

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argument has been fully considered but not deemed persuasive. There appears to be no art of record that would suggest that it would be routine in the art to make and test a representative number of proteins that could be termed "mFLINT" to try to find variants of the disclosed mFLINT protein that would work as required in the claims, and neither could such be expected.

Conclusion

Claims 1-3, 6, 36-39 are not allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is

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(703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m.

The examiner can also normally be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

3/20/03



YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600